Complete Summary

GUIDELINE TITLE

2002 update of recommendations for the use of chemotherapy and radiotherapy protectants: clinical practice guidelines of the American Society of Clinical Oncology.

BIBLIOGRAPHIC SOURCE(S)

Schuchter LM, Hensley ML, Meropol NJ, Winer EP. 2002 update of recommendations for the use of chemotherapy and radiotherapy protectants: clinical practice guidelines of the American Society of Clinical Oncology. J Clin Oncol 2002 Jun 15;20(12):2895-903. [28 references] PubMed

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SCOPE

DISEASE/CONDITION(S)

Toxicity associated with chemotherapy or radiotherapy for cancer:

- Hemorrhagic cystitis associated with use of alkylating agents (ifosfamide and cyclophosphamide)
- Cardiomyopathy associated with the use of anthracycline antibiotics (daunorubicin, doxorubicin)
- Tissue damage (nephrotoxicity, neutropenia, thrombocytopenia, neurotoxicity, ototoxicity, xerostomia, mucositis) due to oxygen-derived free radicals generated by radiation therapy, alkylating agents or platinum agents

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness

CLINICAL SPECIALTY

Oncology
Pharmacology
Radiology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To develop recommendations for the use of mesna, dexrazoxane, and amifostine

TARGET POPULATION

Adult patients with cancer receiving chemotherapy or radiation therapy who are not enrolled in clinical treatment trials

INTERVENTIONS AND PRACTICES CONSIDERED

Use of FDA-approved chemotherapy and radiotherapy protectants:

1. Mesna
2. Dexrazoxane
3. Amifostine

MAJOR OUTCOMES CONSIDERED

- Amelioration of short- and long-term chemotherapy- or radiotherapy-related toxicities
- Risk of tumor protection by the agent
- Toxicity of the protectant agent itself
- Overall and/or disease-free survival
- Quality of life
- Economic impact

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The original guideline was based on pertinent information from the literature published during the time period of 1966 through May 1999 was retrieved and reviewed for the creation of these guidelines. Searches were conducted of MEDLINE and Cancer Lit (National Library of Medicine, Bethesda, MD) to obtain pertinent articles. Search words included amifostine, mesna, and dexrazoxane. Directed searches of the primary articles were performed. In addition, certain

authors/investigators were contacted to obtain more recent and, in some cases, unpublished information.

For the 2002 update, computerized literature searches of MEDLINE and CancerLIT were performed. The searches of the English-language literature form 1997 to 2001included each of the protectants (mesna, dexrazoxane, and amifostine) evaluated in the original guideline. The term "mesna" was combined with "cyclophosphamide," "oral administration," and "ifosfamide"; the term "dexrazoxane" was combined with "breast cancer" and with "cardiac"; and the term "amifostine" was combined with "nephrotoxicity," "neutropenia," "thrombocytopenia," "radiation therapy," "paclitaxel-associated neurotoxicity," and "chemotherapy." The search was further limited to human studies and review articles or randomized controlled trials.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

I. Evidence obtained from meta-analysis of multiple, well-designed, controlled studies. Randomized trials have low false-positive and low false-negative errors (high power)
II. Evidence obtained from at least one well-designed experimental study. Randomized trials have high false-positive and/or false-negative errors (low power)
III. Evidence obtained from well-designed, quasi-experimental studies, such as non-randomized, controlled, single-group, pre-post, cohort, time, or matched case-control series
IV. Evidence from well-designed, non-experimental studies, such as comparative and correlational descriptive and case studies
V. Evidence from case reports and clinical examples

Note: See the previous version of the guideline: American Society of Clinical Oncology Clinical Practice Guidelines for the Use of Chemotherapy and Radiotherapy Protectants J Clin Oncol 2002 Jun 15;20(12):2895-903 for a description of the methods used to assess the quality and strength of the evidence.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

In the original guideline, the collected articles were reviewed by the Panel chairpersons, and appropriate articles were distributed to the entire Panel for review. For the 2002 guideline update, the expert panel co-chairs reviewed the data published since 1998.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The co-chairs drafted the update after review of the pertinent, new literature. The draft update, including guidelines for use, levels of evidence, and grades of recommendation, was circulated to the full expert panel for review and approval. To the extent that the outcome data of interest were available, the Panel placed the greatest value on lesser toxicity that did not carry a concomitant risk of tumor protection.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grade of Evidence for Recommendation

Category A: There is evidence of type I or consistent findings from multiple studies of types II, III, or IV

Category B: There is evidence of types II, III, or IV and findings are generally consistent

Category C: There is evidence of types II, III, or IV, but findings are inconsistent

Category D: There is little or no systematic empirical evidence

Category NG: Grade not given

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines, in draft form, were submitted to independent reviewers.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The American Society of Clinical Oncology (ASCO) updated its 1999 recommendations for the use of chemotherapy and radiotherapy protectants. (American Society of Clinical Oncology Clinical Practice Guidelines for the Use of Chemotherapy and Radiotherapy Protectants. J Clin Oncol, 17(10), 1999: 3333-3355.) Each recommendation from the 1999 guideline is listed below. Unless otherwise indicated, the 1999 guideline remains unchanged based on the review of the most recent evidence. For those recommendations that have changed in the 2002 update, both the original recommendation and the 2002 update are presented.

Chemotherapy and radiotherapy protectants were defined as those agents with potential ability to protect nontumor tissues from the cytotoxic effects of chemotherapy and/or radiotherapy. In this definition, the Panel did not include those agents that may ameliorate known chemotherapy side effects (nausea/vomiting, myelosuppression) but that do not specifically offer nontumor cells protection from the effects of chemotherapy and/or radiotherapy. These guidelines address only those chemotherapy and radiotherapy protectants that are FDA-approved for use in humans.

Levels of evidence (I-V) and grades of evidence (A-D, NG) for recommendations are defined at the end of the Major Recommendation field.

I. Mesna

A. Guidelines for the Use of Mesna as a Urothelial Protectant

1. Mesna Use With Ifosfamide

Guideline: The use of mesna is recommended to decrease the incidence of ifosfamide-associated urothelial toxicity.

Level of Evidence: I

Grade of Recommendation: A

a. Mesna Dosing With Standard-Dose Ifosfamide

Guideline: It is suggested that the daily dose of mesna be calculated to equal 60% of the total daily dose of ifosfamide, administered as three bolus doses given 15 minutes before and 4 and 8 hours after administration of each dose of ifosfamide when the ifosfamide dose is less than 2.5 $g/m^2/d$ administered as a short infusion. For use with continuous infusion ifosfamide, mesna may be administered as a bolus dose equal to 20% of the total ifosfamide dose followed by a continuous infusion of mesna equal to 40% of the ifosfamide dose, continuing for 12 to 24 hours after completion of the ifosfamide infusion.

Level of Evidence: III

Grade of Recommendation: B

b. Mesna Dosing With High-Dose Ifosfamide

Guideline: There is insufficient evidence on which to base a recommendation for the use of mesna with ifosfamide doses in excess of 2.5 g/m ^{2}/d. The efficacy of mesna for urothelial protection with very high-dose ifosfamide has not been proven. Based on the longer half-life of ifosfamide in these dosages, more frequent and prolonged mesna dosage regimens may be necessary for maximum protection from urotoxicity.

Level of Evidence: IV

Grade of Recommendation: D

c. Mesna Administration by the Oral Route

Guideline: Administration of the first dose of mesna intravenously (IV) at a dose equal to 20% of the total daily ifosfamide dose, followed at 2 and 8 hours by 40% weight/weight of the ifosfamide dose administered orally, may be considered an acceptable alternative to the three-dose IV mesna regimen when the total ifosfamide daily dose is less than 2.0 g/m^2.

Level of Evidence: II

Grade of Recommendation: B

2002 Recommendation: Mesna tablets have been approved by the United States Food and Drug Administration (FDA) to prevent hemorrhagic cystitis in patients receiving ifosfamide chemotherapy. The recommended dose and schedule is to administer mesna as an IV bolus injection in a dosage equal to 20% of the ifosfamide dosage (weight/weight) at the time of ifosfamide administration. Mesna tablets are given orally in a dosage equal to 40% of the ifosfamide dose at 2 and 6 hours after each dose of ifosfamide. The total daily dose of mesna is 100% of the ifosfamide dose. Patients who vomit within 2 hours of taking oral mesna should repeat the dose or receive IV mesna. The dosing schedule should be repeated on each day that ifosfamide is administered.

2. Mesna Use With Cyclophosphamide

Guideline: Mesna plus saline diuresis or forced saline diuresis is recommended to decrease the incidence of urothelial toxicity associated with high-dose cyclophosphamide in the setting of stem-cell transplantation.

Level of Evidence: II

Grade of Recommendation: C

3. Surveillance of Patients Receiving Ifosfamide and/or Cyclophosphamide and Mesna

Guideline: There are insufficient data to make a recommendation regarding specific monitoring for hemorrhagic cystitis in patients who receive mesna to ameliorate ifosfamide- or high-dose cyclophosphamide-associated urothelial toxicity. Recommendations for monitoring reflect the design of clinical trials involving mesna use and the opinion of the Panel.

Level of Evidence: V

Grade of Recommendation: D

II. Dexrazoxane

A. Guidelines for the Use of Dexrazoxane

1. Breast Cancer

a. Initial Use in Patients With Metastatic Breast Cancer

Guideline: It is recommended that dexrazoxane not routinely be used for patients with metastatic breast cancer who receive initial doxorubicin-based chemotherapy.

Level of Evidence: II

Grade of Recommendation: C

b. Delayed Use in Patients With Metastatic Breast Cancer Who Have Received More Than 300 mg/m^2 of Doxorubicin

Guideline: It is suggested that the use of dexrazoxane be considered for patients with metastatic breast cancer who have received more than 300 mg/m^2 of doxorubicin in the metastatic setting and who may benefit from continued doxorubicin-containing therapy. Management of patients who have received more than 300 mg/m^2 in the adjuvant setting and are now initiating doxorubicin-based chemotherapy in the metastatic setting should be individualized, with consideration given to (1) the potential for dexrazoxane to decrease response rates,

(2) the risk of cardiac toxicity, and (3) the fact that these patients were not included in the clinical trials of dexrazoxane.

Level of Evidence: III

Grade of Recommendation: B

c. Use in Patients Receiving Adjuvant Chemotherapy for Breast Cancer

Guideline: The use of dexrazoxane in the adjuvant setting is not suggested outside of a clinical trial.

Level of Evidence: V

Grade of Recommendation: Panel Consensus

2. Other Malignancies

a. Use in Adult Patients With Other Malignancies

Guideline: The use of dexrazoxane can be considered in adult patients who have received more than 300 mg/m^2 of doxorubicin-based therapy. Caution should be exercised in the use of dexrazoxane in settings in which doxorubicin-based therapy has been shown to improve survival.

Level of Evidence: III to V

Grade of Recommendation: Panel Consensus

b. Use in Pediatric Malignancies

Guideline: There is insufficient evidence to make a recommendation for use of dexrazoxane in the treatment of pediatric malignancies.

3. Other Anthracycline Doses and Schedules

a. Use in Patients Receiving Other Anthracyclines or Other Anthracycline Dose Schedules

Guideline: The current data regarding the use of dexrazoxane in patients who receive epirubicin-based therapy are insufficient to make a recommendation.

2002 Recommendation: On the basis of the available data and extrapolations from the experience with doxorubicin plus dexrazoxane, the use of dexrazoxane may be considered for patients responding to anthracycline-based chemotherapy for advanced breast

cancer and for whom continued epirubicin therapy is clinically indicated. Data for using dexrazoxane with epirubicin for treatment of other cancers are limited. Data are insufficient to make a recommendation regarding the use of dexrazoxane with other potentially cardiotoxic agents.

b. Use in Patients Receiving High-Dose Anthracycline Therapy

Guideline: There is insufficient evidence on which to base a recommendation for the use of dexrazoxane in patients who receive high-dose anthracycline therapy.

2002 Recommendation: Since data for superior outcomes with high-dose as compared with standard-dose epirubicin treatment for metastatic breast cancer are lacking, and since there are no new data from randomized trials confirming that efficacy of high-dose epirubicin is preserved when given with dexrazoxane, the panel considered the current data for high-dose epirubicin plus dexrazoxane insufficient to make a recommendation.

4. Patients With Cardiac Risks

a. Use in Patients With Cardiac Risk Factors

Guideline: There is insufficient evidence on which to base a recommendation for the use of dexrazoxane in patients with cardiac risk factors or underlying cardiac disease.

5. Monitoring Therapy

a. Termination of Anthracycline Therapy for Patients Receiving Dexrazoxane

Guideline: Patients receiving dexrazoxane should continue to undergo cardiac monitoring. After cumulative doxorubicin doses of 400 mg/m^2 , cardiac monitoring should be frequent. The Panel suggests repeating the monitoring study after a cumulative dose of 500 mg/m^2 is reached and subsequently after every 50 mg/m^2 of doxorubicin. The Panel recommends that the termination of dexrazoxane/doxorubicin therapy be strongly considered in patients who develop a decline in left ventricular ejection fraction to below institutional normal limits or who develop clinical congestive heart failure.

Level of Evidence: V

Grade of Recommendation: Panel Consensus

b. Dose of Dexrazoxane

Guideline: It is suggested that patients who are being treated with dexrazoxane receive dexrazoxane at a ratio of 10:1 with the doxorubicin dose, administered via slow IV push or short IV infusion 15 to 30 minutes before doxorubicin administration.

Level of Evidence: III

Grade of Recommendation: B

2002 Recommendation: It is suggested that patients who are being treated with dexrazoxane receive dexrazoxane at a ratio of 10:1 with the doxorubicin dose, given by slow IV push or short IV infusion, 15 to 30 minutes before doxorubicin or epirubicin administration. A ratio of 10:1 with the epirubicin dose may be reasonable. However, it should be noted that the optimal dose ratio has not been determined.

III. Amifostine

A. Guidelines for the Use of Amifostine

1. Amifostine Use in Chemotherapy-Associated Complications

a. Nephrotoxicity

Guideline: Amifostine may be considered for the prevention of nephrotoxicity in patients who receive cisplatin-based chemotherapy.

Level of Evidence: I

Grade of Recommendation: A

b. Neutropenia and Thrombocytopenia

i. Neutropenia

Guideline: The Panel recommends that amifostine be considered for the reduction of neutropenia-associated events in patients receiving alkylating-agent chemotherapy. However, in the absence of clinical data supporting maintenance of the chemotherapy dose-intensity, physicians should consider chemotherapy dose reduction as an alternative to the use of amifostine.

Level of Evidence: I

Grade of Recommendation: A

ii. Thrombocytopenia

Guideline: Present data are insufficient to recommend the use of amifostine for protection against thrombocytopenia in patients who receive alkylating-agent chemotherapy or carboplatin.

Level of Evidence: II

Grade of Recommendation: B

c. Neurotoxicity and Ototoxicity

Guideline: Present data are insufficient to support the routine use of amifostine for the prevention of cisplatin-associated neurotoxicity or ototoxicity.

Level of Evidence: II

Grade of Recommendation: B

d. Paclitaxel-Associated Neurotoxicity

Guideline: Present data are insufficient to support the use of amifostine for the prevention of paclitaxel-associated neurotoxicity.

Level of Evidence: III

Grade of Recommendation: B

2002 Recommendation: There are no data to support the use of amifostine for prevention of paclitaxel-associated neurotoxicity.

2. Dose and Administration of Amifostine With Chemotherapy

Guideline: In adults, the suggested dose of amifostine with chemotherapy is 910 mg/m^2. Amifostine is administered IV over 15 minutes, 30 minutes before chemotherapy. Administration of amifostine requires close patient monitoring and toxicity is clearly dose-related. All patients should be treated with antiemetics before the administration of amifostine, and pretreatment with IV fluids should also be considered. Blood pressure is measured every 3 to 5 minutes during the 15-minute infusion. Amifostine is discontinued if blood pressure declines significantly or if the patient becomes symptomatic. The hypotension associated with amifostine usually occurs at the end of the infusion and is reversed with discontinuation of the amifostine, administration of saline, and placing the patient in the Trendelenburg position. There are

insufficient data to recommend redosing of amifostine after chemotherapy.

Level of Evidence: I, III

Grade of Recommendation: B

3. Amifostine Use in Radiation Therapy-Associated Complications
   a. Xerostomia and Mucositis
      i. Xerostomia

Guideline: The Panel recommends that amifostine may be considered to decrease the incidence of acute and late xerostomia in patients who undergo fractionated radiation therapy in the head and neck region.

Level of Evidence: I

Grade of Recommendation: A

      ii. Mucositis

Guideline: Present data are insufficient to recommend amifostine to prevent mucositis associated with radiation therapy.

Level of Evidence: I

Grade of Recommendation: C

4. Dose and Administration of Amifostine With Radiation Therapy

Guideline: When given with radiation therapy, the recommended amifostine dose is 200 $mg/m^2/d$ given as a slow IV push over 3 minutes, 15 to 30 minutes before each fraction of radiation therapy. Administration of amifostine requires close patient monitoring, but side effects are fewer at this lower dose. Many patients require antiemetics. Blood pressure should be measured just before and immediately after the 3-minute amifostine infusion. The hypotension associated with amifostine at this dose is less frequent but still requires close monitoring.

Level of Evidence: I

Grade of Recommendation: A

Definitions

Type of Evidence for Recommendation

Level I: Evidence obtained from meta-analysis of multiple well-designed controlled studies; randomized trials with low false-positive and low false-negative errors (high power)

Level II: Evidence obtained from at least one well-designed experimental study; randomized trials with high false-positive and/or negative errors (low power)

Level III: Evidence obtained from well-designed quasi-experimental studies, such as nonrandomized controlled single-group pre-post, cohort, time or matched case-control series

Level IV: Evidence from well-designed nonexperimental studies, such as comparative and correlation descriptive and case studies

Level V: Evidence from case reports and clinical examples

Grade of Evidence for Recommendation

Category A: There is evidence of type I or consistent findings from multiple studies of types II, III, or IV

Category B: There is evidence of types II, III, or IV and findings are generally consistent

Category C: There is evidence of types II, III, or IV, but findings are inconsistent

Category D: There is little or no systematic empirical evidence

Category NG: Grade not given

Note: See the previous version of the guideline "American Society of Clinical Oncology Clinical Practice Guidelines for the Use of Chemotherapy and Radiotherapy Protectants" (J Clin Oncol. 2002 Jun 15;20[12]:2895-903) for a description of the methods used to assess the quality and strength of the evidence.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Mesna Use With Ifosfamide. A double-blind, randomized, placebo-controlled study, a retrospective review of nonrandomized patients, and phase II and observational studies consistently show a decrease incidence of urotoxicity when mesna is used concomitantly with oxazaphosphorines (ie, ifosfamide).
- Mesna Use With Cyclophosphamide. The data are inconsistent regarding the benefit for mesna compared with saline diuresis in patients receiving high-dose cyclophosphamide. Randomized trials show that saline diuresis or mesna plus saline diuresis are superior to continuous bladder irrigation (CBI) for prevention of hemorrhagic cystitis.
- Dexrazoxane. Dexrazoxane has been shown to decrease the incidence of clinical congestive heart failure (CHF) in patients treated with anthracycline agents.

  Initial Use in Patients With Metastatic Breast Cancer. Although the use of dexrazoxane may decrease cardiotoxicity when used at the initiation of doxorubicin-based chemotherapy in breast cancer, the beneficial effects are also seen when the initiation of dexrazoxane is delayed until a cumulative dose of 300 mg/m^2 is reached. Given the potential for increased expense, and possibly increased toxicity, it continues to be reasonable to recommend against the routine use of dexrazoxane at the initiation of doxorubicin-based chemotherapy in patients with metastatic breast cancer. The 1999 guideline erroneously stated that nausea and vomiting were more frequent among patient receiving dexrazoxane compared with those receiving placebo. The data show that the frequency of any-grade nausea and vomiting was higher among placebo patients. There was no significant difference between the two groups in terms of grade 3 nausea or vomiting (P= 0.062; P= 0.52, respectively).

  Delayed Use in Patients With Metastatic Breast Cancer Who Have Received More Than 300 mg/m2 of Doxorubicin. A meta-analysis of seven randomized, controlled trials, two of which were placebo-controlled, addressed the question of the efficacy of dexrazoxane in terms of decreasing the risk of clinical cardiotoxicity. Pooled results from the six studies that had been reported fully in the published literature indicated that the dexrazoxane use was associated with decreased risk of clinical cardiotoxicity (odds ratio, 0.21; 95% confidence interval, 0.09 to 0.5; P = 0.00037).

- Amifostine. There is no evidence from the available clinical data that amifostine leads to protection of tumor (there is a major benefit when a drug protects against normal tissue toxicity and not tumors). In randomized clinical trials, there has been no difference in the overall response rates to treatment, nor any difference in overall survival.

  Xerostomia. Since the publication of the 1999 guideline, the final results of a phase III randomized trial of amifostine as a radioprotector in head and neck cancer were published. This study demonstrated that amifostine reduced acute and chronic xerostomia while preserving antitumor efficacy. Amifostine

reduced the overall incidence of grade 2 or higher acute xerostomia from 78% to 51% (P < .0001). The radiation dose associated with this side effect in 50% of all patients was higher in those patients receiving amifostine compared with those who did not (60 Gy v 42Gy, respectively, P = .001). Chronic xerostomia (symptoms 1 year after completion of treatment) occurred in 34% of patients who received amifostine versus 57% in those who did not (P = .002). Patients who received amifostine also produced more saliva at 1 year compared with those who did not receive treatment. Amifostine was well tolerated. There was no evidence that amifostine interfered with the antitumor effects of radiation therapy as measured by local/regional control and overall survival. Results of a questionnaire study assessing difficulty in speaking and eating, sleep problems and the use of oral comfort aids or fluids in patients treated with amifostine, consistently reported better scores indicative of improved oral toxicity-related outcomes and improved clinical benefit. A small, randomized study demonstrated that amifostine protected against worsening dental health in patients receiving radiation therapy for head and neck cancer.

POTENTIAL HARMS

- Mesna. In doses of up to 70 to 100 mg/kg, mesna was shown to produce no toxic effect on bone marrow, hepatic, renal or CNS functions. Vomiting and diarrhea occurred only after doses of more than 80 mg/kg.
- Dexrazoxane. Side effects include pain on injection and augmented myelosuppression. Concern has been raised about possible interference with the anti-tumor efficacy of doxorubicin therapy. The safety of dexrazoxane use during pregnancy has not been established.
- Amifostine. Nausea, vomiting, and allergic reactions were the most common side effects. Hypotension, usually mild and of short duration, was associated with less than 1% of all amifostine dosages Complications related to venous catheters occurred in 5% of patients treated with amifostine.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- It is important to realize that guidelines cannot always account for individual variation among patients. They are not intended to supplant physician judgment with respect to particular patients or special clinical situations. They cannot be considered to be inclusive of all proper methods of care or exclusive of other treatments reasonably directed at obtaining the same results.
- American Society of Clinical Oncology (ASCO) considers adherence to these guidelines to be voluntary. The ultimate determination regarding their application is to be made by the physician in light of each patient's individual circumstances. In addition, these guidelines describe administration of therapies in clinical practice; they cannot be assumed to apply to interventions performed in the context of clinical trials, given that such clinical studies are designed to test innovative and novel therapies for this symptom in which better treatment is of paramount importance. In that guideline development involves a review and synthesis of the latest literature, practice

guidelines also serve to identify important questions for further research and those settings in which investigational therapy should be considered.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Schuchter LM, Hensley ML, Meropol NJ, Winer EP. 2002 update of recommendations for the use of chemotherapy and radiotherapy protectants: clinical practice guidelines of the American Society of Clinical Oncology. J Clin Oncol 2002 Jun 15;20(12):2895-903. [28 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Oct (revised 2002 Jun)

GUIDELINE DEVELOPER(S)

American Society of Clinical Oncology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Clinical Oncology

GUIDELINE COMMITTEE

American Society of Clinical Oncology Chemotherapy and Radiotherapy Expert Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Conflict of Interest Disclosure Statements

Martee L. Hensley, MD, Co-Chair Research funding from Aventis Oncology and Lilly Oncology provided to Memorial Sloan-Kettering Cancer Center; honoraria from Lilly Oncology and MGI Pharma.
Lynn M. Schuchter, MD, Co-Chair No conflicts noted.
Gail Broder No conflicts noted.
Gary I. Cohen, MD No conflicts noted.
Bahman Emami, MD No conflicts noted.
William J. Gradishar, MD No conflicts noted.
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Robert M. Langdon, MD No conflicts noted.
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Neal J. Meropol, MD No conflicts noted.
R. Brian Mitchell, MD No conflicts noted.
Robert Negrin, MD No conflicts noted.
Ted P. Szatrowski, MD Employed by Roche Laboratories, Inc.
J. Tate Thigpen, MD No conflicts noted.
Daniel VonHoff, MD No conflicts noted.
Todd H. Wasserman, MD Consultant to Medimmunue Oncology for 2 years as well as a member of their Board advisory committee; given various talks for continued medical education organizations and received in excess of $2,000 per year.
Eric P. Winer, MD No conflicts noted.

GUIDELINE STATUS

This is the most current release of the guideline.

This guideline updates a previously released version: J Clin Oncol 1999 Oct;17(10):3333-3355.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available from American Society of Clinical Oncology, Health Services Research, 1900 Duke Street, Suite 200, Alexandria, VA 22314.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Hensley ML, Schuchter LM, Lindley C, et al. American Society of Clinical Oncology Clinical Practice Guidelines for the Use of Chemotherapy and Radiotherapy Protectants. J Clin Oncol 1999 Oct;17(10):3333-3355.

Electronic copies: Available from the American Society of Clinical Oncology (ASCO) Web site.

Print copies: Available from American Society of Clinical Oncology, Health Services Research, 1900 Duke Street, Suite 200, Alexandria, VA 22314.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on January 3, 2000. It was verified by the guideline developer on January 18, 2000. This summary was updated by ECRI on August 28, 2002.

COPYRIGHT STATEMENT

Date Modified: 11/15/2004